

## REMARKS

This amendment is in response to the Official Action mailed July 17, 2007. In the present paper, claims 1, 13, 23 and 24 are amended and claims 8, 20 and 32 are canceled. Claims 1-7, 9-19, 21-31 and 33 are now presented for the Examiner's consideration in view of the following remarks.

### The Present Invention

The inventors have discovered a system and method for identifying and communicating with potential clinical trial participants. The invention permits the use of large, high quality health care databases, such as those containing financial transaction data between health care providers and payers, in locating potential trial participants. Those large-scale databases have not previously been used in the identification of clinical trial participants because of privacy concerns such as those set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Present Specification at paras. [0007]; [0035]).

The invention enables search and correlation of all types of data relevant to clinical trials recruitment by an independent clinical-trials broker ("CTMO").

The present invention permits the use of such databases by replacing identities of the patients in the database with secure patient codes. Once trial candidates have been identified, the secure patient codes are used by a trusted entity to identify and contact the candidates (para. [0052]).

The system and method of the present invention mine financial data created in transactions between health care providers and payers. That financial transaction data has been rigorously scrutinized and verified by those adversarial entities to assure accurate payment of

health care claims, resulting in a high quality database. The present invention takes advantage of that fact, and thereby greatly reduces the high cost of gathering and verifying the medical data. By identifying potential candidates using transaction data that has been arduously analyzed, mistakes are reduced. Before the present invention, no system existed for using that transaction data for identifying clinical trial candidates, while complying with HIPAA privacy regulations.

### Claim Rejections

In the Official Action, the Examiner has rejected claims 1-6, 9-19 and 23-30 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent Publication No. 2002/0099570 to Knight (“Knight”) in view of U.S. Patent Publication No. 2004/0078238 to Thomas et al. (“Thomas”); has rejected claims 7 and 31 under 35 U.S.C. § 103(a) as unpatentable over Knight in view of Thomas and further in view of U.S. Patent Publication No. 2003/0208378 to Thangaraj et al. (“Thangaraj”); has rejected claims 8, 20-21 and 32 under 35 U.S.C. § 103(a) as unpatentable over Knight in view of Thomas and further in view of U.S. Patent No. 6,915,266 to Saeed et al. (“Saeed”); and has rejected claim 22 under 35 U.S.C. § 103(a) as unpatentable over Knight in view of Thomas and further in view of U.S. Patent No. 5,111,395 to Smith et al. (“Smith”).

### The Cited Art

The Knight reference describes a system for recruiting a patient into a clinical trial. Knight performs recruitment in a manner completely different from the present invention: a customized series of questionnaires are presented to a prospective candidate. Knight relies exclusively on physical interaction with the patient through a series of dynamically generated HTML questionnaire forms (Knight, para. [0057]). To maintain a patient’s privacy in such a

system, the clinical trial recruitment would have to be done under a single, strong information-security blanket; i.e., within a single organization.

Thomas describes an anonymizing tool for medical data. The tool permits review of anonymized patient data only within terminals at outside clinics, etc., presumably by healthcare workers. The Thomas disclosure does not teach or suggest any application of its tool to clinical trial candidate recruitment. There is furthermore no teaching or suggestion in Thomas to permit independent organizations to safely broker patient data in a format suitable for clinical trials recruitment.

The Saeed patent is concerned entirely with the processing of administrative data such as billings and collections information, provided by third parties, called “practice management agents” (Saeed, col. 1, lines 8-15). Saeed is not concerned with the use of patient medical records for any purpose. Saeed is unrelated to clinical trial candidate recruitment, and the administrative and billing services described in that reference are unsuitable for that purpose.

### Discussion

In the present paper, each of the independent claims has been amended to incorporate limitations from a dependent claim requiring that the clinical data source include transactions between health care providers and payers. The following discussion focuses on claim 1, which has been amended to incorporate the limitations of claim 8. Applicants submit that the discussion applies to each independent claim.

Applicant asserts that in rejecting claim 8, which contains the limitations now incorporated into amended claim 1, the Examiner has assembled three references using hindsight

provided by the present application, and has pointed to no motivation in the references or elsewhere for one skilled in the art to combine the features as the Examiner has done.

The Examiner has cited the Knight reference as disclosing a method for identifying clinical trial patients, but admits that Knight does not teach replacing identities of patients to allow anonymity (Official Action of 07/17/07 at para. 5). Whether because the issue was ignored or because the entire system was assumed to reside in a single organization, Knight clearly was not concerned with preserving patient anonymity.

Knight furthermore does not use an existing database, but instead builds a new database from data input by the patients themselves (Knight [0052], [0058]). That separate database must be built from scratch and presumably verified at great expense by soliciting each patient in the pool. The pool of potential candidates is limited to those providing data for that purpose, and many or most clinical trial candidates in the general population would be missed. Knight recognizes none of those problems.

To cure the deficiencies of Knight relating to anonymity, the Examiner cites the Thomas reference as teaching the replacement of patient identities with secure patient codes (Official Action at para. 5). The Thomas reference is concerned with the use of DICOM medical image data for research and development purposes. Thomas uses a unique patient identifier to anonymize that medical image data. The technique disclosed by Thomas is unrelated to clinical trials, and one recruiting patients for clinical trials according to the techniques of Knight, which are unconcerned with patient anonymity, would have no reason to consult the Thomas reference.

The Examiner alleges that one would be motivated to combine those references to provide an anonymizing system “with improved patient file continuity.” One in possession of the Knight reference, however, would have no reason to look to Thomas to improve “file

continuity.” The problem of “file continuity” described by Thomas at paragraph [0007], which involves the loss of traceability of multiple records to a specific patient (Thomas, para. [0005]), is a result of anonymizing the data. One practicing the disclosure of Knight, which has nothing to do with anonymizing data, would have no reason to solve Thomas’ “file continuity” problem.

In the rejection of claim 8, the Examiner further admits that neither Knight nor Thomas teaches a “method wherein the database contains transactions” (Official Action at para. 28). The use of a database containing transactions, such as transactions between healthcare providers and payers (specification at [0055]) or transactions from a healthcare insurance claims brokerage (specification at [0063]), provides a very large pool of clinical trial candidates contained in a current, high quality database. Before the development of the present invention, however, such a database was not used in automated clinical trial patient screening because of the privacy problem.

To cure that deficiency of Knight and Thomas, the Examiner cites a third reference, Saeed, as teaching “a database containing transactions between healthcare providers and payers” (Official Action at para. 28). Saeed is concerned with a computerized billing and reimbursement system for processing administrative data among medical service provider systems, coordinator systems and practice management agent systems (Saeed, Abstract; col. 1, lines 30-49), and teaches a payer database 66 and a claims database 68 that are part of a medical service provider system 28 (Saeed, FIG. 8; col. 9, lines 21-29). Saeed provides absolutely no teaching or suggestion to use the databases 66, 68 for anything other than the storage of transaction records within the medical service provider system, and related functions.

The Examiner alleges that it would have been obvious to combine certain features from the Saeed reference with the combination of Knight and Thomas “in order to conduct audits and

information tracking” (Official Action at para. 28). The Examiner cites a Saeed passage stating, “The claims history database 62 includes the administrative data transactions that are used for audits and information tracking” (Saeed, col. 9, lines 27-29).

Applicants assert that Saeed’s teaching to use the administrative data transactions for audits and information tracking provides absolutely no motivation to substitute the Saeed databases for any database in the combination made by the Examiner of Knight and Thomas. First, the Examined has identified no motivation in Knight or Thomas to audit and track data. One practicing the combination of Knight and Thomas made by the Examiner would have no reason to consult Saeed to solve a problem relating to auditing and tracking data.

Further, there is no reason to believe that the administrative data transactions of Saeed are any more suitable for auditing and tracking than the patient data of Knight or the medical image data of Thomas. Indeed, Saeed merely states that the administrative data transactions “are used for audits and information tracking” (Saeed, col. 9, line 28-29). Saeed provides no teaching that its administrative data transactions would be better than any other data for auditing and tracking. Neither Saeed nor either of the other two references in the combination provides any motivation to make the three-way combination made by the Examiner.

Applicants therefore assert that claim 1, as amended, is patentable over the combination of Knight, Thomas and Saeed made by the Examiner at least because there is no suggestion to combine Knight and Thomas, and no suggestion to combine Saeed with the other two. Applicants further submit that claims 2-7 and 9-12, which depend directly or indirectly from claim 1, are patentable for the same reasons.


The remaining independent claims 13, 23 and 24 contain limitations similar to those discussed above with reference to claim 1. Applicants therefore submit that those claims, together with their dependent claims, are patentable for the same reasons.

*Conclusion*

Applicants therefore respectfully assert that claims 1-7, 9-19, 21-31 and 33 and are now in condition for allowance, and earnestly request that the Examiner issue a Notice of Allowance.

Should the Examiner have any questions regarding the present case, the Examiner should not hesitate in contacting the undersigned at the number provided below.

Respectfully,

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